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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte KISHORE C. ACHARYA, DARIN R. OKERLUND, STEVEN J. WOLOSCHEK, and MARK E. WOODFORD

Appeal 2008-1627
Application 10/063,840
Technology Center 3700

Decided: June 19, 2008

Before DONALD E. ADAMS, DEMETRA J. MILLS, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to methods, a medium, and systems for associating EKG waveform data with computed tomography image data using a data synchronization scheme. The Examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 1-30 are pending and on appeal (App. Br. 2-3).[1] Claims 1, 13, 23, 24, and 25, the appealed independent claims, are representative and read as follows:

> 1. A method for associating EKG waveform data with computed tomography image data using a data synchronization scheme comprising:
>
> generating the EKG waveform data using an electrocardiogram device;
>
> operating a computed tomography imaging system so as to create the computed tomography image data;
>
> communicating an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data; and
>
> processing the computed tomography image data, the EKG waveform data and said exposure marker-in signal, so as to correlate the EKG waveform data with the computed tomography image data.
>
> 13. A medium encoded with a machine-readable computer program code for associating EKG waveform data with computed tomography image data using a data synchronization scheme, said medium including instructions for causing a controller to implement a method comprising:
>
> generating the EKG waveform data using an electrocardiogram device;
>
> operating a computed tomography imaging system so as to create the computed tomography image data;
>
> communicating an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data; and
>
> processing the computed tomography image data, the EKG waveform data and said exposure marker-in signal, so as

[1] Appeal Brief filed October 10, 2006.

to correlate the EKG waveform data with the computer tomography image data.

23. A method for associating EKG waveform data with image data generated by an imaging system using a data synchronization scheme comprising:

obtaining the imaging system, an electrocardiogram device and an object to be examined;

associating said object with the imaging system and said electrocardiogram device; and

processing the image data and the EKG waveform data using the data synchronization scheme wherein the data synchronization scheme,

generates the EKG waveform data using an electrocardiogram device;

operates the imaging system so as to create the image data;

communicates an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data; and

processes the image data, the EKG waveform data and said exposure marker-in signal, so as to correlate the EKG waveform data with the image data.

24. A system for associating EKG waveform data with computed tomography image data using a data synchronization scheme comprising:

a gantry having an x-ray source and a radiation detector array, wherein said gantry defines an object cavity and wherein said x-ray source and said radiation detector array are rotatingly associated with said gantry so as to be separated by said object cavity;

an object support structure movingly associated with said gantry so as to allow communication with said object cavity; and

a processing device having the data synchronization scheme, wherein the data synchronization scheme,

generates the EKG waveform data using an electrocardiogram device;

operates a computed tomography imaging system so as to create the computed tomography image data;

communicates an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data; and

processes the computed tomography image data, the EKG waveform data and said exposure marker-in signal, so as to correlate the EKG waveform data with the computer tomography image data.

25. A system for associating EKG waveform data with image data using a data synchronization scheme comprising:

an imaging system;

an object disposed so as to be communicated with said imaging system, wherein said imaging system generates image data responsive to said object; and

a processing device having the data synchronization scheme, wherein the data synchronization scheme,

generates the EKG waveform data using an electrocardiogram device;

operates said imaging system so as to create the image data;

communicates an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data; and

processes the image data, the EKG waveform data and said exposure marker-in signal, so as to correlate the EKG waveform data with the image data.

The Examiner relies on the following reference as evidence of unpatentability:

Heuscher	US 6,154,516	Nov. 28, 2000

The following rejection is before us for review:

Claims 1-30 stand rejected under 35 U.S.C. § 102(b) as anticipated by Heuscher (Ans. 5-6).

ANTICIPATION

ISSUE

The Examiner cites Heuscher as disclosing "a method and system where EKG waveform data is used to gate of time a medical image device wherein the medical imaging device is a computed tomography image system" (Ans. 5). The Examiner states that "image acquisition begins by first generating ECG or EKG waveform data using electrocardiogram device 80, 104 (figures 1 and 2) and operating CT imaging system 10 to create CT images and communicating the EKG waveform data associated with the CT image data" (*id.* (citing Heuscher, col. 2, ll. 13-24; col. 2, l. 62 through col. 3, l. 8; col. 4, l. 7 through col. 7, l. 59)). The Examiner states that Heuscher also discloses "an image memory medium 66, which stores image data with the correlated EKG or ECG waveform" (Ans. 6).

Appellants point out that "[i]ndependent Claims 1, 13, 23, 24 and 25, each include the limitation of: '. . . *communicating an exposure marker-in signal to said electrocardiogram device* such that said exposure marker-in signal is associated with the EKG waveform data . . .'" (App. Br. 6). Appellants contend that the Examiner has not shown that Heuscher inherently meets that limitation, nor has the Examiner "shown with specificity where Heuscher discloses both an *exposure marker-in signal*, as claimed, and *communication of the exposure marker-in signal to the electrocardiogram device*" (*id.* at 7).

The issue, then, is whether the Examiner erred in finding that Heuscher meets the limitation in independent claims 1, 13, 23, 24 and 25, requiring an "exposure marker-in signal" to be communicated to the electrocardiogram device "such that said marker-in signal is associated with the EKG waveform data."

FINDINGS OF FACT ("FF")

1. Claim 1 recites a method for associating EKG waveform data with computed tomography image data. The method uses a data synchronization scheme in which EKG waveform data are generated using an electrocardiogram, and computed tomography image data are created by operating a computed tomography imaging system.

The method also requires "communicating an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data." The computed tomography image data, the EKG waveform data, and the exposure marker-in signal, are then processed so as to correlate the EKG waveform data with the computed tomography image data.

2. Claim 13 recites a medium encoded with a machine-readable computer program code for associating EKG waveform data with computed tomography image data using a data synchronization scheme. The medium includes instructions for causing a controller to essentially implement the method recited in claim 1, including the step of "communicating an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data."

3. Similar to claim 1, claim 23 recites a method for associating EKG waveform data with image data generated by an imaging system. Like claim

1, claim 23 requires using a data synchronization scheme that "communicates an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data."

4. Claims 24 and 25 recite systems for associating EKG waveform data with computed tomography image data using a data synchronization scheme. Claims 24 and 25 both require their respective systems to have a data synchronization scheme that "communicates an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data."

5. The Specification describes an "exposure marker-in signal" as follows (Spec. [0025]):

> As CT imaging system 4 begins to operate, CT imaging system 4 generates a CT event signal herein referred to as exposure marker-in signal 228, wherein exposure marker-in signal 228 is a negative impulse signal. Exposure marker-in signal 228 is then communicated to EKG monitoring device 2 via EKG sync marker input 8 so as to overlay EKG waveform data 200 and indicate the start of a CT scan. Although exposure marker-in signal 228 is preferably a negative impulse signal, exposure marker-in signal 228 may be any signal suitable to the desired end purpose. In addition, although exposure marker-in signal 228 is preferably generated via CT imaging system 4, exposure marker-in signal 228 may be generated via any device and/or method suitable to the desired end purpose.

6. Heuscher discloses:

> [A] method for cardiac gated spiral CT [(computed tomography)] imaging is provided. The method includes assessing a breath hold time for a patient, measuring an average heart rate of the patient, and determining a range of scan coverage. Next, based on results from the initial steps, a

> patient-specific scan protocol is selected. In accordance with the selected scan protocol, a spiral CT scan of the patient is performed while collecting ECG data from the patient. The ECG data is used to correlate phases of the patient's heart with x-ray data collected via the spiral CT scan. Ultimately, an image representation of a region of interest of the patient at a point in time corresponding to a selected phase of the patient's heart is reconstructed from the x-ray data collected.

(Heuscher, col. 2, l. 63, though col. 3, l. 8.)

7. Figure 1 of Heuscher, reproduced below, "is a diagrammatic illustration of a cardiac gated spiral CT scanner in accordance with aspects of the present invention" (Heuscher, col. 3, ll. 65-67):

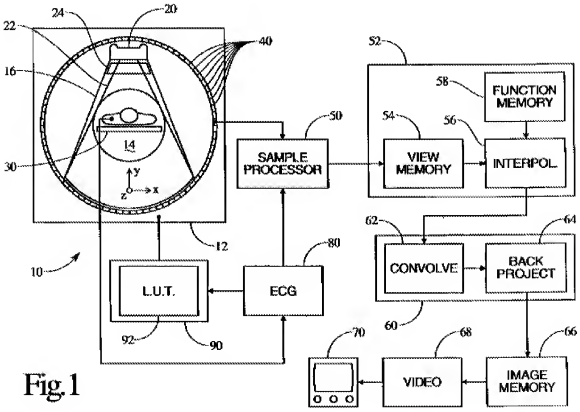

Fig. 1

Figure 1 shows ECG (electrocardiogram) monitor 80 acquiring ECG data via leads attached to the patient in the examination region 14 (*see* Heuscher, col. 5, ll. 54-55). "The ECG data is used to accurately correlate phases of the patient's heart with data collected by the radiation detectors 40. More specifically, in a preferred embodiment, the sampling processor 50 tags sampled data views with the ECG data" (*id.* at col. 5, ll. 55-60).

Heuscher also discloses that ECG monitor 80 communicates the patient's average heart rate to control processor 90, the control processor in turn using that information along with other patient data to access a suitable scanning protocol for the patient from a "look up table" 92 ("L.U.T." in Figure 1), which is then implemented (*see* Heuscher, col. 5, l. 61, through col. 6, l. 9).

8. Heuscher discloses that, since the ECG monitor acquires data simultaneously with the CT scanner, "[i]n one embodiment, prior to the scan, a calibration is performed to account for any latency between delivery of the ECG data and the data collected from the radiation detectors 40" (Heuscher, col. 7, ll. 23-26). Using this calibration, "the sampling processor 50 tags each sampled fan view of data with the ECG amplitude and it is saved as part of every fan view such that various phases of the heart are accurately correlated to the view data" (*id.* at col. 7, ll. 26-30).

PRINCIPLES OF LAW

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). During examination, the PTO must interpret terms in a claim using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

ANALYSIS

We agree with Appellants that the Examiner has not shown that Heuscher meets the limitation of "communicating an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data."

The Specification provides that, "[a]s the CT imaging system begins to operate," it generates "a CT event signal herein referred to as [an] exposure marker-in signal" (Spec. [0025] (FF 5)). Thus, as Appellants use the term, an "exposure marker-in signal" is a signal of an event in the CT imaging system, for example, the start of a CT scan. The Specification also notes that, although preferably generated by the CT imaging system, this signal of a CT system event "may be generated via any device and/or method suitable to the desired end purpose" (*id.*).

We agree with the Examiner that Heuscher's methods and systems correlate EKG data and image data obtained from a CT scanning device (*see* FF 6-8). However, we do not agree with the Examiner that Heuscher

discloses communicating a signal of a CT imaging system event to the electrocardiogram device, as required by the claims.

Specifically, Figure 1 of Heuscher discloses that, rather than communicating any information to the ECG monitor 80, the data collected by the CT system's radiation collectors 40 is communicated to sample processor 50, which "tags sampled data views with the ECG data" (Heuscher, col. 5, ll. 59-60 (FF 7)). Thus, rather than communicating any signal of a CT event to the electrocardiogram device, the data from Heuscher's CT imaging system is communicated to a third device, the sample processor 50.

Moreover, although the sample processor 50 uses the data obtained *from* the ECG monitor 80 to tag the image data and thereby correlate the images with the phases of the heart (*see* FF 7, 8), we see nothing in Heuscher disclosing that any component communicates *to* the ECG monitor 80 any signal of an event in the CT imaging system. Rather, from viewing Figure 1, it is apparent that the only input to the ECG monitor 80 disclosed by Heuscher is from the patient via the attached leads (*see* FF 7). We therefore agree with Appellants that Heuscher does not explicitly disclose the claimed limitation of "communicating an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data."

The Examiner argues that Heuscher meets that limitation because "the CT image acquisition is gated by ECG or EKG where the gating provides specific phase, in other words, marker in the ECG or EKG" (Ans. 4). We do not agree.

As discussed above, while Heuscher's electrocardiogram monitor 80 provides data to allow correlation of the heart's phases with the image data, including tagging of the image data with the EKG information, Heuscher simply does not disclose that any signal regarding any event in the CT imaging system is sent to electrocardiogram monitor 80 (*see* FF 6-8).

The Examiner argues that Heuscher inherently meets the limitation at issue because "Heuscher et al's scanning includes specific protocol where the control of the CT scan use look up table to assess patient characteristic ECG, i.e. ECG waveform and phase in which the CT scan acquires the images" (Ans. 4 (citing Heuscher, col. 5, l. 61 through col. 6, l. 9)). We are not persuaded by this argument.

We agree with the Examiner that Heuscher's ECG monitor 80 communicates the patient's average heart rate to control processor 90, and that the control processor in turn uses the ECG data along with other patient data to access a suitable scanning protocol for the patient from a "look up table" 92 ("L.U.T." in Figure 1) (*see* FF 7). However, as is evident from viewing Figure 1 and its supporting disclosure, ECG monitor 80 transmits data to control process 90 rather than receiving any communication regarding a CT imaging event. Because Heuscher does not disclose that either control processor 90 or look up table 92 communicates any signal or data to ECG monitor 80, the Examiner's argument does not persuade us that Heuscher inherently meets the limitation of "communicating an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data."

The Examiner argues that "[t]he inherency of cardiac gating with imaging technique is to communicate triggering of the imaging system with

ECG/EKG and vice versa" (Ans. 6-7). The Examiner urges that the "triggering event is critical for the CT image reconstruction in Heuscher et al or any other cardiac imaging technique. Whether the imaging system or ECG/EKG system triggers the image acquisition, the image date and reconstruction is correlated to ECG/EKG signal so that the image reconstruction is correlated to a specific phase of the ECG/EKG wave" (*id.* at 7). The Examiner reasons that such a triggering event is inherent in Heuscher's system because, "without the communication between the so-called 'exposure marker-in signal' (which is merely triggering event) is necessary in order for the images and ECG/EKG data to be correlated. Otherwise, the imaging system's reconstruction is blind to the cardiac phase, thus image reconstruction cannot be made based on the cardiac phase without the triggering event" (*id.*).

We are not persuaded by this argument. Even assuming for argument's sake that communication of a triggering event is essential to systems that correlate cardiac image data with EKG, we do not agree with the Examiner that Heuscher's system functions by communicating a signal regarding a CT image event *to the electrocardiogram device* as required by the appealed claims. Rather, as discussed above, the electrocardiogram data and the image data are transmitted to a separate component, sample processor 50, which correlates the data from the two sources (*see* FF 7). Thus, while it may be true that a signal regarding a CT event is transmitted to the sample processor 50, we do not agree with the Examiner that the necessity of a triggering event means that Heuscher's system functions by sending such a signal to the electrocardiogram device.

In sum, we agree with Appellants that the Examiner has not shown that Heuscher explicitly or inherently meets the limitation of "communicating an exposure marker-in signal to said electrocardiogram device such that said exposure marker-in signal is associated with the EKG waveform data." Because we agree with Appellants that the Examiner has not shown that Heuscher discloses performing that step, or discloses configuring its systems in a manner such that they can perform that step, we reverse the Examiner's anticipation rejection of independent claims 1, 13, 23, 24, and 25, and their dependent claims, 2-12, 14-22, and 26-30.

REVERSED

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